SECTION 6
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
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Marlborough, MA 01752

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AUG 0 9 2013

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Date Prepared: February 22, 2013

2. Proposed Device:

Trade Name: MaxForce Biliary Balloon Dilatation Catheter
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: Hurricane RX Biliary Balloon Dilatation Catheter
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Trade Name: MaxForce Biliary Balloon Dilatation Catheter (K910931)
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: Hurricane RX Biliary Balloon Dilatation Catheter (K001338)
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

4. Device Description:

MaxForce Biliary Balloon Dilatation Catheter: The MaxForce Biliary balloon dilatation catheter, styled after the Gruntzig technique, is a double lumen catheter with a non-compliant balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow duct segments as well as the Sphincter of Oddi.

Hurricane RX Biliary Balloon Dilatation Catheter: The Hurricane RX Biliary Balloon Dilatation Catheter is a double lumen catheter with a balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow duct segments, as well as the Sphincter of Oddi.

5. Indications for Use:

MaxForce Biliary Dilatation Catheter: The MaxForce Biliary Balloon Dilatation Catheters are recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi.

Hurricane RX Biliary Balloon Dilatation Catheter: The Hurricane RX Biliary Balloon Dilatation Catheter is recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi. The Hurricane RX Biliary Balloon Dilatation Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

6. Technological Characteristics:

The resin of the "catheter tip" component of the MaxForce Biliary and Hurricane RX products are being slightly modified. The current resin is being discontinued by the supplier and will be replaced with a similar resin.

7. Performance Data:

Technical assessments were performed to demonstrate that the performances of the two resins are equivalent. The following tests were conducted:

- Guidewire Compatibility
- Multiple Inflation
- Proximal Balloon Bond Tensile
- Wing Tool Removal Force
- Shaft Lap Weld Tensile Strength
- Balloon Rated Burst Pressure
- Biocompatibility Testing

All tests had passing results.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed "catheter tip" resin is substantially equivalent to the "catheter tip" resin of the currently cleared MaxForce Biliary (K910931) and Hurricane RX Biliary Catheter (K001338) devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Boston Scientific Corporation
% Andrew Nguyen
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K130484
Trade/Device Name: MaxForce Biliary Dilatation Catheter
Hurricane RX Biliary Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 5, 2013
Received: July 10, 2013

Dear Andrew Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130484

Device Name: MaxForce Biliary Dilatation Catheter
Hurricane RX Biliary Catheter

Indications for Use:

MaxForce Biliary Dilatation Catheter: The MaxForce Biliary Balloon Dilatation Catheters are recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi.

Hurricane RX Biliary Balloon Dilatation Catheter: The Hurricane RX Biliary Balloon Dilatation Catheter is recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi. The Hurricane RX Biliary Balloon Dilatation Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130484